The Commissioner is hereby authorized to charge underpayment of any fees (including any filing fees under 37 C.F.R. §1.16 for additional claims and any patent application processing fees under 37 C.F.R. §1.17 including any fee for extension of time) associated with this communication or credit any overpayment to Deposit Account No. 01-0272. A duplicate copy of this authorization is enclosed.

Respectfully Submitted
on behalf of Applicant,

Date: 12-04-01

Steven J. Adamson
Reg. No. 32,776

Steven J. Adamson, PC
P.O. Box 5997
Portland, OR 97228
Tel: 503.248.0100
Fax: 503.248.0105
sja@ip-rights.com

Attorney Docket No.:
Doc't No:

Separate, marked-up version of amended paragraphs (§1.121(b)):
In the Specification:

Amend the paragraph beginning at page 3, line 20, to read as follows:

It is believed that these or other conditions cause the digestive tract of a person with autism to function sub-optimally. Two important pioneers of this work, Reichelt and Shattock, observed a significant correlation between the symptoms of autism and an impaired ability to adequately digest peptides/proteins from dairy (casein) and wheat (gluten). During digestion, pre-opioid type compounds in the diet, typically from casein and gluten, are thought to be activated due to an incomplete breakdown of proteins. These exorphins (i.e., casomorphins and gluteomorphins or [gliadorphin] gliadinomorphin) are then easily transferred across the lumen of the gut into the circulation where they exert opioid-type action on the brain.

Amend the paragraph beginning at page 4, line 25, to read as follows:

To compensate for the apparent lack of sufficient quantities of DPPIV and to generally rebuild proper functioning of an autistic individual's intestinal tract with regard to absorption and digestion, different approaches have been employed. Of these, enzyme therapy and probiotic supplementation have been favored and met a degree of success.

Enzyme therapy was developed, in part, through the pioneering work of Dr. Jon Pangborn and Dr. Bernard Rimland, working on behalf of the Autism Research Institute (ARI). These researchers recognized the need for and developed an enzyme composition that cleaves gluteopmorphins such as Gly-Tyr-Tyr-Pro-Thr and related sequences, and casomorphins such as Tyr-Pro-Phe-Pro and related sequences (see publication entitled *Peptidase Enzyme Digestive Aid Project*, by Pangborn, J., published at ARI's 3rd Annual Defeat Autism Now! Conference, September, 1997. Enzyme therapy has typically been based on supplementation with large amounts of proteases from [the] different categories of proteolytic enzymes and these have included acid or carboxyl peptidases, peptidases with both endo- and exo-

peptidase activity, and serine, cystein and zinc proteases. More recently (following the work of Pangborn and Rimland), exogenic DPPIV from animal (usually cow or pig) and plant sources has been utilized. While enzyme therapy has had limited success, it is disadvantageous, amongst other reasons, in that many proteases, including DPPIV, are substantially broken down in the stomach and do not reach the intestines in a functional state.

Insert the following new paragraph at page 6, line 26:

In one embodiment the present invention includes a composition that has a physiologically effective amount of a purified genomeceutical material of the type that affects expression of a DPPIV like compounds when ingested by a human in such a manner as to relieve symptoms of autism, and one or more of a purified protease, a purified peptidase that exhibits DPPIV like activity or a purified phytase. The genomeceutical material may be galactose or glucans or other similarly functioning material. The peptidase may be DPPIV or QPP. The protease may be an acid fast protease or a cystein protease. The composition may also include a purified phospholipid containing substance, a purified disaccharidase and/or a purified lipase.

In another embodiment, the present invention includes a composition that has a purified phytase like compound, and a physiologically effective amount of one or more of a purified genomeceutical for treating autism or a purified peptidase that exhibits DPPIV like activity for treating autism. This composition may also include an acid fast protease, a purified phospholipid containing material and/or a purified lipase. The genomeceutical may include at least one of purified galactose or purified glucans.

In yet another embodiment, the present invention includes a method of preparing a composition for treatment of autism that has the steps of: providing a physiologically effective amount of a purified genomeceutical material of the type that affects expression of a DPPIV like compounds when ingested by a human in such a manner as to relieve symptoms of autism; providing at least one of a purified protease, a purified peptidase that exhibits DPPIV like activity or a purified phytase; and mixing said purified genomeceutical and said one of said

purified protease, peptidase or phytase to achieve a compound effective in treating symptoms of autism. The step of providing a purified genomeceutical may include the step of providing at least one of purified galactose and purified glucans, while the step of providing a purified protease may include the step of providing at least one of a purified acid fast protease and a purified cystein protease.

Insert the following new paragraphs at page 7, line 2:

The following quoted terms and phrases are defined as follows. "Composition" refers to a combination of multiple substances into an aggregate mixture. "Purified" indicates that a substance is provided in a state that is more pure than that substance occurs in its natural state, though a "purified" substance may contain other active or inactive material. "Physiologically effective amount" refers to an amount of an active substance that is sufficient to achieve an externally observable effect on a patient.

Amend the paragraph beginning at page 8, line 25, to read as follows:

If, in autistic individuals, the DPPIV gene has been silenced or attenuated (i.e., down-regulated), then the addition of galactose has the potential to reverse or circumvent the down-regulation. This positive regulation may occur not only in human intestinal wall cells (enterocytes), but in other cells where DPPIV or DPPIV-like enzymes are expressed (where a DPPIV-like enzyme is an enzyme that cleaves proline-containing peptide bonds in exorphins). It should also be recognized that DPPIV or like expression in cells other than human enterocyte cells may [proved] prove to be as or more beneficial than enterocyte cell expression. These other cells include, but not limited to, peripheral blood (immune) cells and other cells with suitable surface architectures and signaling cascades.

Amend the paragraph beginning at page 10, line 17, to read as follows:

The components are generally available commercially and are preferably provided in a dry form, mixed and encapsulated, though

other delivery methods may be utilized without departing from the present invention. The capsules are preferably taken with food. While the presence and concentration of the above ingredients may vary widely (as discussed to some extent herein below and as recognized by one skilled in the art given the teachings herein), in one embodiment formulation A may contain the following:

1. galactose 100mg;
2. bromelain concentrate 230 BTU;
3. acid fast protease 100 SAPU;
4. peptidase concentrate 10,000 AU;
5. lactase 300 LACU; and
6. phytase 125 PU.

It should be recognized that these values are intended to be representative and in no way limit [to] the present invention.

Amend the paragraph beginning at page 12, line 18, to read as follows:

It should be recognized that while Formulation A preferably has at least the six listed [six] ingredients, the present invention may include combinations of less than all of the listed ingredients (or alternative components as discussed below), as determined by the limits of prior art. For example, the combination of a GC for treating autism and proteases/peptidase is within the present invention as is the combination of a GC for treating autism and phytase or a phytase like compound. If a patient does not have milk in their diet or is not lactose intolerant then lactase may not be necessary. Further variations are suggested elsewhere herein and others yet would be apparent to skilled practitioners given the teachings herein. Given the exponential combination of ingredients all variations are not specifically called out, though it should be recognized that they are intended to fall within the present invention.

Amend the paragraph beginning at page 12, line 18, to read as follows:

Thus, including one of these sugars or a related compound as a substitute for or in addition to the galactose of Formulation A or with

any variation of the components [or] of Formulation A or their analogues or any other variation alluded to herein is within the present invention.

Separate, marked-up version of amended claims (§1.121(c)):

1 (amended). A composition for treating autism, comprising:

a physiologically effective amount of a purified genomeceutical material of the type that affects expression of a DPPIV like compounds when ingested by a human in such a manner as to relieve symptoms of autism; and

one or more of a purified protease, a purified peptidase that exhibits DPPIV like activity or a purified phytase.

4 (amended). The composition of claim 1, wherein said genomeceutical material includes a purified milk sugar other than galactose.

8 (amended). The composition of claim 1, comprising both [a] said protease and [a] said phytase.

9 (amended). The composition of [claims] claim 1, further including a purified phospholipid [promoting compound] containing substance.

10 (amended). The composition of [claims] claim 1, further including a purified disaccharidase [compound].

11 (amended). The composition of [claims] claim 1, further including purified lipase [compound].

12 (amended). A composition for treating autism, comprising:

a purified phytase like compound; and

a physiologically effective amount of one or more of a purified genomeceutical for treating autism or a [protease] purified peptidase that exhibits DPPIV like activity for treating autism.